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05/04/04 11:47 AM

To: NCIC HPV@EPA

CC:

Subject: Fw: Environmental Defense comments on Benzene Phosphorous Dichloride (CAS# 644-97-3) and Benzene Phosphinic acid (CAS# 1779-48-2)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 05/04/2004 11:47 AM -----



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05/04/2004 11:02 AM

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Subject: Environmental Defense comments on Benzene Phosphorous Dichloride (CAS# 644-97-3) and Benzene Phosphinic acid (CAS# 1779-48-2)

(Submitted via Internet 5/4/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and william.smock@verizon.net)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Benzene Phosphorous Dichloride (BPD) and Benzene Phosphinic acid (BPA).

The test plan and robust summaries on BPD (CAS# 644-97-3) and BPA (CAS# 1779-48-2) were submitted by the BPD/BPA Coalition. This coalition is comprised of three companies; Avecia, Inc., Ferro Corporation and Akzo-Nobel Functional Chemicals. The test plan states that these companies are the only known manufacturers of BPD and BPA.

The test plan states that almost all of the BPD is converted to BPA, which is used primarily in nylon applications and in the synthesis of flame retardants. Furthermore, data presented in the test plan and robust summaries indicate that BPD is rapidly hydrolyzed under biological conditions to BPA. The sponsor proposes that BPA and BPD should be considered as a category because of structural similarities and the rapid conversion of BPD to BPA. We agree with the category designation for BPD and BPA, based on the justification provided in the test plan.

The available data for BPA and BPD are sparse, so the sponsor proposes conducting a number of studies to fill data gaps in the SIDS endpoints. We agree with the sponsor's proposals to conduct the additional studies indicated in the test plan. However, we disagree with the sponsor's claim that repeat dose, reproductive and developmental toxicity studies cannot be performed because of animal welfare concerns. The reasons specified in the test plan are that (1) BPA causes gastrointestinal hemorrhaging and gastritis even at low oral doses administered in bolus, and (2) BPA is a strong skin irritant, so dermal studies are not recommended. However, the test plan also states that the NOEL found in a 14-day feeding study was 860 mg/kg. The NOEL was estimated after detailed histological analysis, including of the gastrointestinal tract. Therefore, animal welfare issues should not prevent the sponsor from conducting a combined repeat dose/reproductive/developmental toxicity study on BPD using doses as high as 1000mg/kg in feed. Since BPD and BPA constitute a category, the results from the BPD study can be used to estimate BPA toxicity values.

Other comments are as follows:

1. The sponsor presents considerable data indicating that BPA can be a very dangerous chemical. How are workers protected from the toxic effects of BPA?
2. Are there not opportunities for consumer exposures to BPA or BPD, given the wide array of products that use these chemicals in their manufacturing processes?

3. The sponsor proposes to conduct ecotoxicity studies on BPA instead of BPD, since BPD is rapidly hydrolyzed to BPA and the acidic properties of BPA will be buffered in aquatic media. However, since BPD is converted not only to BPA, but also to PPOA and PP, the results using BPD would have broader utility than if BPA were used, which is not converted to PPOA and PP. Therefore, we recommend using BPD as the test substance.

4. The test plan indicates that there are two other hydrolysis products from BPD: phosphinic acid (PPOA) and phenyl phosphine (PP). We agree that PPOA can be considered in the same category as BPA and BPD for HPV purposes and that it is not practical to test PP because it is pyrophoric.

5. BPD exhibits in vitro mutagenicity but no in vivo data are available, so the sponsor proposes to conduct an in vivo mutagenicity study on BPA. While we agree that an in vivo study is needed, why not use BPD as the test sample? Since BPD is rapidly converted to BPA, PPOA and PP the results using BPD would have broader utility than if BPA were used, which is not converted to PPOA and PP. Therefore, we recommend using BPD as the test substance in the in vivo mutagenicity study.

6. The sponsor contends that the mechanism of action for BPD and BPA is the acidic properties of these chemicals. This conclusion is premature as toxicities other than gastrointestinal hemorrhaging might be detected in the repeat dose/reproductive/developmental toxicity study.

Thank you for this opportunity to comment.

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